agents to prepare a facility safety program plan based on the criteria below and submit the plan to the contracting agency for review prior to beginning BDP contract operations. The plan will describe the contractor organization, and procedures for meeting DOD, Army, and contracting Command safety requirements as specified in the contract.

(1) A safety training program for all individuals working with etiologic agents must be documented by the contractor and include, as a minimum, the requirements in § 626.7(e). Appropriate safety training will be provided to scientists, other laboratory personnel, and unrelated personnel such as technicians, clerical, and maintenance workers. This training will be documented.

(2) The contractor must designate a qualified individual to be responsible for the entire safety program with full authority to develop and enforce contractor safety policies. Regular safety inspections will be conducted and inspection reports will be provided to the contracting agency upon request.

(3) Policies for storing, handling, and moving etiologic agents within the contractor facility shall be included in the plan.

(4) Policies and procedures for disposal of any etiologic agent waste must be identified. Disposal must comply with Federal, State, and local regulations as well as DOD and Army requirements.

(5) An SOP must be established for each area where BDP etiologic agents are stored, transferred, or used. In addition, an SOP must be prepared for operations unique to any specific contract. The contractor will provide the SOP to contracting agency personnel upon request for review.

(6) For contracts requiring BL–3 or BL–4, the contractor will provide (upon request) facility engineering drawings and specifications for the relevant etiologic agent containment areas, associated ventilation systems, and local approving authority. Also to be included is test data verifying that all systems adequately meet the DOD and Army safety requirements, as well as test methods for periodic recertification of the system.

(7) MCE scenarios that ensure that all realistic threats are considered at contractor sites, see § 626.12 of this part.

### § 626.17 Contractor changes.

The contractor will submit proposed changes to the original safety documentation to the contracting agency for review prior to implementation. Requests will include justification and test data verifying that adequate safety will be maintained.

### § 626.18 BDP contract requirements.

(a) Contractors performing work with BL–3 and BL–4 material must prepare a plan detailing procedures for controlling laboratory mishaps involving etiologic agents.

(1) The contractor shall have the necessary equipment and trained personnel for controlling the mishap.

(2) In the event of an incidental release of a BDP etiologic agent from appropriate laboratory biocontainment that may result in personnel exposure, approved emergency procedures will be initiated immediately to effectively protect personnel and the environment and to constrain the spread of contamination. The affected areas will be decontaminated before normal operations are resumed.

(3) Special medical surveillance will be started as soon as possible for all workers present in the potentially affected area at the time of the mishap.

(4) Local emergency support agencies, such as law enforcement, fire departments, health departments, and governments will be informed of BDP activities and the appropriate support necessary, to include any equipment and training to provide effective emergency response. Agreements with external agencies must be formalized.

(5) The contractor shall be required to review the plan annually and consult external agencies if there is an agreement for them to provide assistance. This should be done in coordination with the contracting agency.

(b) [Reserved]

## Subpart D—BDP Studies and Reviews

### § 626.19 Assuring maximum safety.

(a) Safety studies and reviews are conducted to assure that maximum safety and health measures are being taken to prevent mishaps involving BDP etiologic agents in any amount or under any conditions that may cause incapacitation, illness, or death to any person, or adverse effects on the public or to the environment.

(b) The system safety requirements of AR 385–16 will be followed during all BDP safety studies and reviews.

### § 626.20 Special studies.

Any HQDA agency may recommend a special study or review of an etiologic agent or system when it becomes necessary to investigate the condition or changes described below. The responsbile HQDA agency will determine the scope and conduct the study or review. Special study activities will be coordinated with HQDA, DACS–SF, WASH DC 20310–0200.

(a) Conditions or practices which may affect safety.

(b) Major system modifications including both design and physical configuration changes.

(c) Significant changes to safety, health, and environmental protection standards and requirements that affect BDP operations.

### APPENDIX A TO PART 626—REFERENCES

These publications can be obtained from the National Technical Information Services, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161.

#### REQUIRED PUBLICATIONS

AR 40–5—Preventive Medicine. (Cited §626.7(f) introductory text)
AR 40–400—Patient Administration. (Cited in §626.6)
AR 385–10—Army Safety Program. (Cited in §§626.4(c) introductory text, 626.4(g)(3), and 626.4(g)(5))
AR 385–16—System Safety Engineering and Management. (Cited in §§626.11, and 626.19)
AR 385–40—Accident Reporting and Records. (Cited in §§626.4(c)(10) and 626.6)
AR 415–15—Military Construction, Army (MCA) Program Development. (Cited in §626.11)
DA Pam 385–69—Biological Defense Safety Program. (Cited in §§626.1(b), 626.4(g)(3), 626.4(g)(4), 626.5(b), 626.7(h)(1), 626.7(i) intro text, 626.7(i)(1), 626.7(k), 626.8(b), 626.10(a), 626.10(b), and 626.16(b))
Med 16 Report. (Cited in §626.6)

#### RELATED PUBLICATIONS

A related publication is merely a source of additional information. The user does not have to read it to understand this regulation.

AR 40–10—Health Hazard Assessment Program in Support of the Army Material Acquisition Decision Process
AR 70–1—Systems Acquisition Policy and Procedures
AR 70–10—Test and Evaluation During Development and Acquisition of Materiel
AR 70–18—The Use of Animals in DOD Programs
AR 70–25—Use of Volunteers as Subjects of Research
AR 70–65—Management of Controlled Substances, Ethyl Alcohol, and Hazardous Biological Substances in Army Research, Development, Test, and Evaluation Facilities
AR 200–1—Environmental Protection and Enhancement
AR 200–2—Environmental Effects of Army Actions
AR 405–90—Disposal of Real Estate

### APPENDIX B TO PART 626—GLOSSARY ABBREVIATIONS

AMC—United States Army Materiel Command
AR—Army regulation
ARSTAF—Army Staff
ASA (IL&E)—Assistant Secretary of the Army (Installations, Logistics and Environment)
ASA (RDA)—Assistant Secretary of the Army (Research, Development, and Acquisition)
BDP—Biological Defense Program
BL—Biosafety level
CG—commanding general
CSA—Chief of Staff, United States Army
DA—Department of the Army
DA Pam—Department of the Army Pamphlet
DASAF—Director of Army Safety
DCSOPS—Deputy Chief of Staff for Operations and Plans
DOD—Department of Defense
HEPA—high efficiency particulate air
HQDA—Headquarters, Department of Army
IPR—in process reviews
MACOM—major Army command
MCA—Military Construction, Army
MCE—maximum credible event
OCSA—Office of the Chief of Staff, United States Army
R&D—research and development
RDTE—research, development, test, and evaluation
RCRA—Resource Conservation Recovery Act